



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

September 28, 1999

Connie McNabb
Regulatory Affairs Associate
Mallinckrodt Inc.
675 McDonnell Blvd.
P.O. Box 5840
St. Louis, MO 63134

Dear Ms. McNabb:

Your petition requesting the Food and Drug Administration to make a determination that an Abbreviated New Drug Application may be submitted for Hydrocodone Bitartrate and Acetaminophen Tablets, USP (5 mg/325 mg) for product that has been determined to be safe and effective, yet has never been marketed, was received by this office on September 28, 1999. It was assigned docket number 99P-4209/CP 1 and it was filed on September 28, 1999. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

99P-4209

ACK1